

ITU

PATENT Customer No. 22,852 Attorney Docket No. 07579.0015-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Graham Edmund KELLY et al.) Group Art Unit: 1614
Application No.: 10/600,004) Examiner: Cybille DELACROIX-) MUIRHEID
Filed: June 18, 2003) Confirmation No. 6037
For: COMPOSITIONS FOR)
CARDIOVASCULAR AND BONE)
TREATMENT USING)
FORMONONETIN AND OTHER)
ISOFLAVONES (as amended))

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

Applicants enclose the following papers for filing in the above-referenced application:

- 1) Amendment and Response (14 pages);
- 2) Petition for Three Month Extension of Time (1 page);
- 3) Declaration under 37 C.F.R. § 1.132 of Graham Edmund Kelly (3 pages);
- 4) Copy of the Assignment and Notice of Recordation for Application No. 10/600,004 (4 pages);
- 5) Copy of the Assignment and Notice of Recordation for Application No. 09/077,590 (now U.S. Patent No. 6,340,703) (3 pages);
- 6) Declaration under 37 C.F.R. § 1.132 of Alan J. Husband (2 pages);
- 7) Copy of the Assignment and Notice of Recordation for Application No. 10/600,004 (4 pages);

- 8) Terminal Disclaimer (4 pages);
- 9) Annual Report (61 pages);
- 10) Second Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97(c) (4 pages);
- 11) Form PTO 1449 (19 pages);
- 12) Copies of two hundred and twenty (220) listed documents,
- 13) Third Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97(c) (3 pages);
- 14) Form PTO 1449 (1 page);
- 15) Copies of five (5) listed documents,
- 16) Fourth Notice Regarding Related Litigation (4 pages);
- 17) Plaintiff Solae's Third Supplemental Complaint (13 pages);
- 18) Defendant ADM's Answer and Counter Claims to Plaintiff's Third Supplemental Complaint (10 pages);
- 19) Defendant Amerifit's Answer and Counter Claims to Plaintiff's Third Supplemental Complaint (11 pages);
- 20) Plaintiff's Reply to Answer and Counterclaims of Defendant Amerifit (6 pages);
- 21) Plaintiff's Reply to Answer and Counterclaims of Defendant ADM (6 pages);
- 22) Docket Report for Civil Case No. 4:03-CV-00732-HEA ("Solae I") printed September 27, 2004 (12 pages);
- 23) Docket Report for Civil Case No. 4:03-CV-01595 HEA ("Solae II") printed September 27, 2004 (6 pages); and
- 24) Check for \$1,510.00 for the following fees:
 - a. \$1,020.00 extension fees,
 - b. \$360.00 fee for the submission of two Information Disclosure Statements under 1.97(c),
 - c. \$130.00 disclaimer fee.

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If there is any additional fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: December 13, 2004

Deborah J. Acker

Reg. No. 48,916



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Graham Edmund KELLY et al.) Group Art Unit: 1614
Application No.: 10/600,004) Examiner: Cybille DELACROIX-MUIRHEID
Filing Date: June 18, 2003) Confirmation No. 6037
For: COMPOSITIONS FOR CARDIOVASCULAR AND BONE TREATMENT USING FORMONONETIN AND OTHER ISOFLAVONES (as amended)))))))

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Sir:

FOURTH NOTICE REGARDING RELATED LITIGATION

Applicants hereby submit this Fourth Notice Regarding Related Litigation to the U.S. Patent and Trademark Office to inform the Office of the current status of the Solae I and Solae II litigations. The present application, U.S. Serial No. 10/600,004, filed June 18, 2003, is a continuation of U.S. Application No. 09/914,035, filed as PCT/AU00/00384 on April 27, 2000, which entered the national stage on December 10, 2001, and is now abandoned. Although the instant application and the patents in suit do not share a common specification or overlapping claims to priority, in the utmost caution, the Applicants submit this notice in the event that the disclosures in

the respective specifications would ever be considered related. Application Nos. 10/600,004 and 09/914,035 are assigned to Novogen Research Pty. Ltd. ("Novogen").

Applicants previously submitted three Notices Regarding Related Litigation, on September 11, 2003, on December 23, 2003, and on May 3, 2004, informing the Office that on June 3, 2003, Solae, L.L.C. ("Solae") filed a Complaint alleging that Archer Daniels Midland Company ("ADM") and Amerifit Nutrition, Inc. ("Amerifit") infringe at least one claim of U.S. Patent No. 6,562,380 ("the '380 patent") and U.S. Patent No. 5,990,291 ("the '291 patent"). The case, Civil Case No. 4:03-CV-00732-HEA, was filed in U.S. District Court for the Eastern District of Missouri ("Solae I"). The '380 patent issued from U.S. Application No. 08/910,837 on May 13, 2003, and was originally filed on August 13, 1997, as a continuation of U.S. Patent Application No. 08/338,567, filed January 12, 1995, now U.S. Patent No. 5,830,887. The '291 patent is a divisional of U.S. Patent Application No. 09/086,658, filed on May 29, 1998, now U.S. Patent No. 5,919,921, which issued on July 6, 1999, which is a continuation-in-part of U.S. Patent Application No. 08/661,845, filed on June 11, 1996, now U.S. Patent No. 5,821,361.

Applicants also informed the Office that on November 4, 2003, Solae filed a separate Complaint alleging that ADM and Amerifit infringe at least one claim of the U.S. Patent No. 6,642,212 B1 ("the '212 patent"). The case, Civil Case No. 4:03-CV-01595 HEA, was filed in U.S. District Court for the Eastern District of Missouri ("Solae II"). The '212 patent issued from U.S. Patent Application No. 09/421,069 on November 4, 2003, and was originally filed on October 19, 1999, as a continuation of U.S. Patent Application No. 08/910,837, filed August 13, 1997, now U.S. Patent No. 6,562,380 B1. In this Complaint Solae also alleged infringement of U.S. Patent No. 6,664,382 B1 ("the '382 patent"), issued December 16, 2003. On January 29, 2004, Solae filed a Second Supplemental Complaint adding a claim of infringement of U.S.

Patent No. 6,680,381 ("the '381 patent") to the earlier allegations of infringement of '212 and '382 patents.

We highlight the following events in the Solae litigation, which have occurred since the events summarized in our previous Notice Regarding Related Litigation of May 3, 2004.

On April 26, 2004, Solae filed its Third Supplemental Complaint adding an allegation of infringement of U.S. Patent No. 6,706,292 ("the '292 patent") to the earlier presented allegations of infringement of the '212, the '382, and the '381 patents.

On April 28, 2004, the Court ordered consolidation of Solae I and Solae II cases for all purposes. All further pleading related to allegations in Solae II will be filed in Civil Case No. 4:03-CV-00732-HEA (Solae I).

On May 11, 2004, Defendants ADM and Amerifit filed Answers and Counter Claims to Plaintiff's Third Supplemental Complaint. In these answers ADM and Amerifit deny all allegations presented in Third Supplemental Complaint and present claims of invalidity and non-infringement of '212, '382, '381, and '292 patents.

On June 1, 2004, Solae filed Plaintiff's Replies to Answers and Counterclaims of Defendants ADM and Amerifit. In these Replies Solae denied defendants' allegations of non-infringement and invalidity of '212, '382, '381, and '292 patents.

On August 20, 2004, ADM filed Motion for Protective Order which was granted on August 26, 2004.

Further to this Notice, the Applicants attach: Plaintiff Solae's Third Supplemental Complaint; Defendant ADM's Answer and Counter Claims to Plaintiff's Third Supplemental Complaint; Defendant Amerifit's Answer and Counter Claims to Plaintiff's Third Supplemental Complaint; Plaintiff's Reply to Answer and Counterclaims of Defendant Amerifit; Plaintiff's

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Reply to Answer and Counterclaims of Defendant ADM; and docket reports for Solae I and Solae II cases, current as of September 27, 2004.

REMARKS

As stated above, the present application and the patents in suit do not share a common specification nor overlapping claims to priority although they do relate to isoflavones and are all assigned to Novogen Research Pty. Ltd. Nevertheless, to avoid even the appearance of impropriety, Applicants submit this Notice in the event that the disclosures in the respective specifications would ever be considered related.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,

GARRETT & DUNNER, L.L.P.

Dated: December 13, 2004

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